1646

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit – 1646

In re

Patent Application of

Leslie A. Holladay

Serial No.: 10/016,403

Filed: December 10, 2001

Confirmation No.: 4840

Examiner: Ruixiang, Li

"MODIFICATION OF POLYPEPTIDE DRUGS TO INCREASE ELECTROTRANSPORT FLUX"

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Leslie Restaro
Signature

December 2, 2002
Date

#9
M.Q.J
12/30/02

RESPONSE TO ELECTIONS/RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

This is in response to Office Action mailed October 31, 2002. The Office Action is being timely responded to because the due date of November 30, 2002 is a Saturday.

The Examiner identified three groups of claims: Group I claims 1, 2,4, 17 and 18, drawn to a method for delivering a pharmaceutical polypeptide agent through a body surface, classified in class 514, subclass 2;

Group II claim 5, drawn to a method of modifying a pharmaceutical polypeptide agent to enhance electrotransport through a body surface, classification depends upon the method used to produce the agent; and

Group III claims 6-15, drawn to a synthetic analog of a parent polypeptide and a composition comprising such a synthetic analog, classified in class 514, subclass 2.

In response to the above-noted restriction requirement, Applicant elects Group I claims 1, 2, 4, 7 and 18 with traverse.

Applicant hereby traverses the restriction requirement in its entirety. Restriction is only proper where "two or more independent and distinct inventions are claimed in one application." (35 U.S.C. §121). Applicant respectfully submits that the three groups of claims identified by the Examiner in the Office Action are not directed to "independent and

distinct inventions," but to different embodiments of the same invention. The present invention consists of a method of delivering a pharmaceutical polypeptide agent through a body surface, a method of modifying a polypeptide to provide enhanced electrotransport of same through a body surface, and the synthetic analogs thereof. All of the above-related claim embodiments intimately relate to each other. Together they form the working basis for the claimed invention. Separately, they do not have the necessary core of the invention to relate to. Thus restriction to any of the groups of claims is improper, under 35 U.S.C. §121.

Applicant further submits that even if the claim groups were directed to independent or distinct inventions, rather than to embodiments of the same invention, restriction would not be appropriate in this case for the following reasons. The Manual of Patent Examining Procedure ("MPEP") states that:

> "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." MPEP §803.

Applicant respectfully submits that all claims of the present application could be examined together without placing any serious burden on the U.S. Patent and Trademark Office ("Patent Office"). The claims are inextricably related to one another that, for the sake of efficiency, they should be examined in a single application. A complete search of the prior art relating to these claims would necessarily require a search of all the subject matter of all the groups. Given the close relationship between the claims, prosecution in the same application would be administratively efficient for the Patent Office.

Applicant submits that with the argument presented herein, claim 5, and 6-15 are not directed to separate and distinct inventions, but to the same invention, and therefore restriction is improper. Withdrawal of restriction of claims 5, and 6-15 is respectfully requested.

Date: 12/2/02

Grady J. Frenchick
Attorney for Applicant
Reg. No. 29,018

Docket No.: 011293-9028
MICHAEL BEST & FRIEDRICH LLP
One South Pinckney Street, Suite 700
P. O. Box 1806
Madison, Wisconsin 53701-1806
(608) 257-3501